

REMARKS

Applicants thank the Examiner for the courtesy extended to Applicants' attorney during the interview held July 12, 2004, in the above-identified application. During the interview, Applicants' attorney explained the presently-claimed invention and discussed the issues raised in the Office Action. The discussion is summarized and expanded upon below.

The provisional rejection of Claim 1 under the judicially created doctrine of obviousness-type double patenting over Claim 1 of copending Application Serial No. 10/030,161 (copending application), is respectfully traversed. Claim 1 of the copending application requires that  $R^3$  be lower alkyl which has one or more hydroxy or protected hydroxyl. The above-amended claims, on the other hand, while inclusive of substituted lower alkyl as a possible constituent for  $R^3$ , nevertheless, exclude hydroxyl and protected hydroxyl. There is no disclosure or suggestion in Claim 1 or any of the claims of the copending application to replace the hydroxy or protected hydroxy therein for  $R^3$  with any other group. Accordingly, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 9-12 under 35 U.S.C. § 112, first paragraph, is respectfully traversed. The rejection of Claims 10 and 11 is moot in view of the cancellation of these claims. With regard to Claim 9, the term "pharmaceutical" has been deleted as suggested by the Examiner, although no change in claim scope is intended or effected. With regard to above-amended Claim 12, support appears in the specification at pages 56-58. Finally, although not apparently relevant to the rejection, there is **no** ambiguity between the use of Example 5, which is described in the specification at page 240, and subjected to a test as described in the specification at page 56, on the one hand, and Preparation No. 5, described in the specification at page 63, the meaning of which is described in the specification at page 60, last paragraph.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 8, 10 and 12 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. The rejection of Claim 10 is moot in view of the cancellation of said claim. Regarding Claim 8, the term "reducting" has been corrected to --reducing--.

Regarding the Examiner's particular reference to a process calling for reduction of the nitrile to the corresponding amine, note that Claim 8 recites seven alternative processes. Of these seven processes, only process i) and v) begin with a nitrile-containing starting material. In process i), the  $C \equiv N$  group is reduced to an  $NH_2$  group. In process v),  $C \equiv N$  is reduced and then reacted with a compound having the formula  $R_C^3 - OH$ , to produce an  $NH-R_C^3$  group. In other words, there is no process that produces a **substituted amino group directly** from a nitrile precursor.

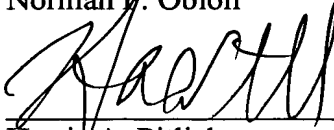
For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejection of Claim 10 under 35 U.S.C. § 101 is now moot in view of the cancellation of said claim. Accordingly, it is respectfully requested that the rejection be withdrawn.

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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